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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 12/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/916,257	Applicant(s) SHAPIRO, ALLA	
	Examiner Shahnam Sharareh	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/24/2002, 7/30/01* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *10-16 and 26-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 17-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2,4,6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-9, 17-25 in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the field of search is overlapping and there is no additional burden on the Examiner to search all of the pending claims. This is not found persuasive because as recited in the Requirement, Paper No. 5, the inventions are unrelated as they have different effects or modes of operation. Furthermore, different classification of the Groups is prima facia evidence of burdensome search.

Thus, the requirement is still deemed proper and is therefore made FINAL.

2. Claims 10-16, 26-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 5.

This application contains claims 10-16, 26-28 drawn to an invention nonelected with traverse in Paper No. 5. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of treating the effects of radiation by administering to a mammal isoflavone, does not reasonably provide enablement for methods of preventing the effects of radiation in any mammal. Accordingly, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Ex parte Forman (230 USPQ 546, BdPatApp & Int.) and *In re Wands* (858 F.2d 731, 8 USPQ2d 1400, 1404, Fed. Cir. 1988) provide several factors in determining whether the specification of an application allows the skilled artisan to practice the invention without undue experimentation. Having said factors in mind, the instant specification fails to reasonably provide enablement for methods of preventing the claimed condition. Specifically, the recitation of "preventing the effects of radiation" in the instant claim 1, direct the claims to methods of preventing a pathological condition. However, the specification fails to properly enable such methods.

In the instant case, the burden of enabling for preventing the formation of a pathological condition requires appropriate screening testing, subsequent data compilation, and finally appropriate data analysis, to assess and properly enable one skill in the art whether wrinkles are prevented from formation in a patient. For example, the specification must provide adequate guidance whether radiation side effects can be prevented from forming in a patient or in this case, a mammal, once the composition is administered to a subject susceptible to develop such side effects.

Moreover, the specification must provide direct evidence associating the claimed prevention to the composition applied. The burden of showing preventative properties is greater than that of enabling a treatment, because one of ordinary skill in the art must not only show competent screening of those subjects susceptible to such conditions, but also show that the efficacy of a preventative method is directly caused by applying or administering the instantly claimed composition to the susceptible subjects.

In this case, there are no teachings for screening methods identifying susceptible subjects nor is there any direct evidence of efficacy establishing a preventative property associated with the claimed composition. Furthermore, the state of the prior art concerning methods of preventing adverse effects associated with radiation is not described, nor does it provide for any absolute level of prevention. Accordingly, undue experimentation is necessary to determine screening and testing protocols to demonstrate the efficacy of the presently claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-9, 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. The recitation of "methods of preventing the effects of radiation" is ambiguous as it is not clear what the scope of said term is? Neither the claim nor the specification specifies what is meant by "preventing the effects of radiation, nor is such limitation a known methodology in the art. Thus, the metes and bounds of the claims are not clear.

6. The recitation of "isoflavone derivatives" in claims 6 and 20 renders the scope of the claim indefinite, because it is not clear to which derivatives is applicant referring? Isoflavone derivatives encompass a many different possibilities of such compounds, the scope of which is not well defined in the specification. Accordingly, the metes and bounds of the claims are not clear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-9, 17-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Wei US Patent 5,824,702.

The instant claims are directed to methods of treating the effects of radiation in a mammal exposed to radiation comprising administering to said mammal a therapeutic effective amount of an isoflavone.

Wei discloses methods of preventing the harmful effects of UVR exposure to human skin comprising applying a therapeutic effect of genistein to the skin of a subject. (see abstract). Wei discloses administeration of genisten one hour prior to UV exposure (see col 4, lines 24-26; claims 2-5). UV is recognized among ionizing radiation, thus

meeting the limitation of the instantly recited radiation (see for example attached US Patent 6,423,747 at col 1, lines 54-59). Accordingly, Wei anticipates the limitations of the instant claims.

8. Claims 1-5, 7-9, 17-21, 23-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Lanzendorefer et al US Patent 6,423,747.

Lanzendorfer discloses methods of applying genistein to skin to restablish the epidermal barrier function of the skin (see claims 1-5, and col 20, lines 33-36). Lanzendorfer's method related to process for protecting skin from exposures to UV rays (see col 15, line 26-40). UV rays are recognized as ionizing radiation (see col 1, lines 54-60), thus meeting the limitations of the instantly claimed radiation exposure. Therefore, Lanzendorfer anticipates the limitations of the instant claims.

9. Claims 1-9, 17-25 are rejected under 35 U.S.C. 102(e) as being anticipated by de Juan Jr. US Patent 6,399,655.

De Juan discloses methods of propholactically treating an animal for cataract comprising systemically administering genistein to an animal and wherein the cateract is caused by exposure to radiation or toxicity thereof (see col 10, lines 40-55; col 11, lines 4-7). Accordingly, de Juan anticipates the limitations of the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 1-9, 17-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wei et al (PSEBM 1995, vol 208, 124, 1995) in view of de Juan Jr, US Patent 6,399,655.

Wei teaches the use of genistein in inhibiting radiation induced tumor (see abstract). Wei speculates that protective mechanism of genistein also may be applied to for treating X-irradiation associated side effects because such side effects are caused by H2O2 stimulation of MAP kinase activity and formation of ROS (see p. 129, 1st col) and genistein therapeutic effects are caused by inhibitions of ROS generation. Wei fails to teach oral administration of genistein.

De Juan is solely used to show that systemic application of genistein is well established in the art (cols 9-11).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to administer genistein for treating x-ray radiation associated side effects and further as described by de Juan optimize the useful oral doses by routine experimentation. One of ordiary skll in the art would have been motivated to do such

modifications because as suggested by Wei genistein would have been expected to alleviate side effects caused by x-ray radiation.

Conclusion

11. No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200

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December 9, 2002